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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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G.E. EHRLICH (1995) LTD.
c/o ANTHONY CASTORINA
SUITE 207
2001 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202

EXAMINER	
DECLOUX, AMY M	
ART UNIT	**PAPER NUMBER**
1644	9

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/944,602	Applicant(s) PECKER ET AL.	
	Examiner Amy M. DeCloux	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 7-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: see note in office action regarding drawings with color photos.

DETAILED ACTION

Claims 1-10 are pending.

Election/Restrictions

Applicant's election of Group II, claims 3-6, and the species of the method of determining whether a patient has CLL as recited in claim 3, in Paper No. 8, filed 11-29-02, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-2 and 7-10 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

It is noted that Figures 1, 2b, 9a-f, 10A-f, 11A-F, 12A-f, 13, 20, 21a-b, 22a-b and 23a-c are in color.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information

submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specifically a list of references is disclosed on pages 73-80 of the instant specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented.

Claim 3 is drawn to a method of determining if a patient has CLL comprising monitoring heparanase expression in blood cells from a patient and based on the presence or absence of said expression, determining whether the patient has CLL.

Claim 4 is drawn to a method of determining if a patient has NHL comprising monitoring heparanase expression in blood cells from a patient and based on the presence or absence of said expression, determining whether the patient has NHL.

Claim 5 is drawn to a method of determining if a patient has AML comprising monitoring heparanase expression in blood cells from a patient and based on the presence or absence of said expression, determining whether the patient has AML.

Claim 6 is drawn to a method of determining if a patient has ALL comprising monitoring heparanase expression in blood cells from a patient and based on the presence or absence of said expression, determining whether the patient has ALL.

The specification discloses that when peripheral white blood cells from patients with CML, ALL, NHL or AML were tested for the expression of the human hpa gene by rtPCR, said cells from CML patients and from NHL patients showed no detectable expression of the hpa gene, while said cells from all 14 AML patients tested expressed the human hpa gene, as did said cells from both ALL patients tested, (Figure 13 and page 56). However, it is clear that the claimed method alone is insufficient to determine whether a patient has one of CML, ALL, NHL or AML because there are four diseases and only two results (expression or non-expression of

the hpa gene by white blood cells). Therefore one of skill could not distinguish whether a patient had AML or ALL based solely on a test that indicated the hpa gene was expressed in white blood cells because both are positive for hpa gene expression. Therefore it is clear that additional factors must be considered when determining whether a patient has one of said diseases, and said factors are known to one of skill as indicated by the methods of diagnosing CML, ALL, NHL or AML, as taught by pages 946 and 959-960 of the 17th Edition of the Merck Manual.

It is noted that the expression of hpa in blood cells other than white blood cells is not disclosed to have been tested for use in determining whether a patient has CLL, AML, ALL or NHL, and that the specification discloses on page 30, that heparanase expression is strong in healthy neutrophils and platelets. Also it is noted that the specification discloses a method comprising the detection of the expression of the human heparanase gene of SEQ ID NO:1, in human patients, but not any other heparanase gene. The specification discloses on pages 10-11 the potential existence of other human heparanases distinct from the human heparanase encoded by the instant SEQ ID NO:1, but that one said other human heparanase is expressed in human placenta. Also the specification does not disclose that the heparanase encoded by SEQ ID NO:1 is expressed in species other than human. As evidenced by Merck Manual, the art at the time the invention was made does not show a method comprising the expression of any heparanase gene including that encoded by SEQ ID NO:1, in any blood cells, in any species to determine if a patient has CLL, AML, ALL or NHL. Therefore, it would require undue experimentation for one of skill to use the recited methods comprising any heparanase other than that encoded by SEQ ID NO:1, in any blood cells other than white blood cells, in any species other than human, without consideration of other diagnostic indicators to determine if a patient has CLL, AML, ALL or NHL, without further guidance and direction from the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-6 are indefinite in the recitation of the phrase "a patient" recited in line 3 of each claim because it is unclear if the phrase reads on the subject of the preamble recited in line 1 of each respective claim. Replacing the word "a" in said phrase with the word "said" is one way to overcome the rejection.

Conclusion

No art was found on the recited methods.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux 2-9-03
Amy DeCloux, Ph.D.,
Patent Examiner,
Group 1640
February 9, 2003